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Registration Decision

RD2014-20

Halosulfuron, present as methyl ester

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Registration Decision for Halosulfuron, present as methyl ester

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Halosulfuron Technical Herbicide and the end-use products Sandea Herbicide, Permit Herbicide and SedgeHammer Turf Herbicide, containing the technical grade active ingredient halosulfuron, present as methyl ester (henceforth referred to as halosulfuron-methyl), for use in a broad range of field and horticultural crops for the control of yellow nutsedge and broadleaved weeds.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document¹ Proposed Registration Decision PRD2014-05, *Halosulfuron, present as methyl ester*. This Registration Decision² describes this stage of the PMRA's regulatory process for halosulfuron-methyl and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2014-05. This decision is consistent with the proposed registration decision stated in PRD2014-05.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2014-05, *Halosulfuron, present as methyl ester* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable³ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value⁴ when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

³ "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Halosulfuron-methyl?

Halosulfuron-methyl is a Herbicide Resistance Action Committee (HRAC) Group B active ingredient commonly known as an inhibitor of acetolactate synthase, a key enzyme in plants. Halosulfuron-methyl is a selective herbicide for use in a broad range of field and horticultural crops for the control of yellow nutsedge and broadleaved weeds. Halosulfuron-methyl will be available as three commercial class end-use products: Sandea Herbicide (horticultural crop use); Permit Herbicide (field crop use); and SedgeHammer Turf Herbicide (turf and ornamental uses).

Health Considerations

Can Approved Uses of Halosulfuron-methyl Affect Human Health?

Products containing halosulfuron-methyl are unlikely to affect your health when used according to label directions.

Potential exposure to halosulfuron-methyl may occur through the diet (food and water) or when handling and applying the products. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

In laboratory animals, the technical grade active ingredient halosulfuron-methyl was of low acute oral, dermal and inhalation toxicity. It was minimally irritating to the eyes and non-irritating to the skin. Halosulfuron-methyl did not cause an allergic skin reaction.

The end-use products containing halosulfuron-methyl (Sanda, Permit and SedgeHammer Turf Herbicides) were slightly acutely toxic by the oral route and mildly irritating to the eyes; consequently, the hazard signal words "CAUTION – POISON" and "EYE IRRITANT" are required on the label. They were of low acute toxicity through both dermal and inhalation exposure, slightly irritating to the skin and did not cause an allergic skin reaction.

Halosulfuron-methyl did not cause cancer in animals and did not damage genetic material. Effects on the nervous system were seen in the rats and dogs at dose levels resulting in mortality. At doses toxic to the mothers, treatment with halosulfuron-methyl produced stillbirths and reduced pup survival and birth weights. Health effects in animals given repeated doses of halosulfuron-methyl included effects on body weight in all species, effects on the liver in rats and effects on the blood-forming system in dogs.

When halosulfuron-methyl was given to pregnant animals, increased embryofetal mortality and malformations of the tail and ribs in the developing fetus were observed at doses that were toxic to the mother. Because of these concerns, extra protective factors were applied in the risk assessment to further reduce the allowable level of human exposure to halosulfuron-methyl.

The risk assessment protects against the effects of halosulfuron-methyl by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Risks in Residential and Other Non-Occupational Environments

Residential and non-occupational risks are not of concern when SedgeHammer Turf Herbicide is used according to the proposed label directions.

Adults, youth and children may be exposed to halosulfuron-methyl while golfing on courses and conducting various activities on residential turf treated with SedgeHammer Turf Herbicide. Based on the expected short- to intermediate-term duration of this activity, risk to children, youth and adults is not a concern.

Occupational Risks From Handling Sandea Herbicide, Permit Herbicide, and SedgeHammer Turf Herbicide

Occupational risks are not of concern when Sandea Herbicide, Permit Herbicide, and SedgeHammer Turf Herbicide are used according to the proposed label directions, which include protective measures.

Farmers, custom applicators, and commercial applicators who mix, load or apply Sandea Herbicide, Permit Herbicide, or SedgeHammer Turf Herbicide as well as field workers re-entering freshly treated fields, orchards, commercial and residential turf, landscaped areas, nurseries, and industrial areas can come into direct contact with halosulfuron-methyl residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying Sandea Herbicide, Permit Herbicide, or SedgeHammer Turf Herbicide must wear a long-sleeved shirt and long pants (or coveralls), chemical-resistant gloves, shoes and socks. Anyone who

mixes/loads and applies SedgeHammer Turf Herbicide must wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, shoes and socks when treating roadsides and other industrial areas for horsetail with a mechanically-pressurized handgun. The Permit Herbicide label also requires that workers do not enter treated fields to detassel seed corn for 14 days after application. For other re-entry activities, the Sandea Herbicide and Permit Herbicide labels require that workers do not enter treated fields or orchards for 12 hours after application. The SedgeHammer Turf Herbicide label requires that workers do not enter treated areas until sprays have dried. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the risk to these individuals are not a concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Residues in Water and Food

Dietary risks from food and drinking water are not of health concern.

Aggregate dietary intake estimates (food plus drinking water) revealed that the general population and children 1-2 years old, the subpopulation which would ingest the most halosulfuron-methyl relative to body weight, are expected to be exposed to less than 5% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from halosulfuron-methyl is not of health concern for all population subgroups.

Halosulfuron-methyl is not carcinogenic; therefore, a cancer dietary risk assessment is not required.

Acute dietary (food plus drinking water) intake estimates for the females 13-49 years of age were less than 1% of the acute reference dose, and are not of health concern.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout the United States, which included growing regions representative of Canada, using halosulfuron-methyl on apples, highbush blueberries, raspberries, blackberries, rhubarb, asparagus, peppers (bell and non bell), tomatoes, cantaloupe, cucumber, summer squash, succulent snap beans, almonds, pecans, pistachios, dry beans, sweet corn, field corn, grain sorghum and proso millet are acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of PRD2014-05, *Halosulfuron, present as methyl ester*.

Environmental Considerations

What Happens When Halosulfuron-methyl Is Introduced Into the Environment?

Halosulfuron-methyl can pose a risk to freshwater algae and non-target terrestrial and aquatic vascular plants; therefore, statements on the product labels are required to inform users of the potential risks, and spray buffer zones are required during application.

Halosulfuron-methyl enters the environment when applied to control weeds on various field crops and non-crop areas. Halosulfuron-methyl can break down by reacting with water or in the presence of soil microbes and is unlikely to persist in terrestrial systems. Despite having properties that indicate a potential for leaching, field studies, monitoring and modelling data indicate that if halosulfuron-methyl reaches groundwater, levels are expected to be low. In aquatic environments, halosulfuron-methyl is rapidly broken down and is not expected to move into sediment or accumulate in aquatic organisms. Halosulfuron-methyl is also unlikely to enter the atmosphere. Although laboratory data indicate that breakdown products of halosulfuron-methyl are mobile and persistent, results from terrestrial field dissipation studies show little vertical movement and relatively quick dissipation.

When used according to the label directions, halosulfuron-methyl will pose a negligible risk to earthworms, bees, birds, small mammals, fish and aquatic invertebrates. Halosulfuron-methyl can pose a risk to freshwater algae and to non-target terrestrial and aquatic vascular plants. Risks to freshwater algae and non-target terrestrial and aquatic vascular plants can be mitigated with label statements and spray buffer zones to protect sensitive terrestrial and aquatic habitats. Runoff of halosulfuron-methyl into water bodies may pose a risk to freshwater algae and aquatic vascular plants. Label statements are required on the product labels to inform users of the potential risks.

Value Considerations

What Is the Value of Sandea Herbicide, Permit Herbicide and SedgeHammer Turf Herbicide?

Yellow nutsedge is a difficult-to-control perennial weed and chemical control options are lacking in almost all crops.

The registration of Sandea, Permit, and SedgeHammer Turf Herbicides will provide Canadian growers access to an active ingredient registered for many years in the United States, and will satisfy numerous weed control priorities found in the Canadian Grower Priority Database including: dry bean (high); apple (intermediate); highbush blueberry (high); asparagus (high); eggplant (high); tomatoes (high); pumpkin (high); squash (high); cucumber (high); snap bean (high); pecan (high); chestnut (intermediate).

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Sandea Herbicide, Permit Herbicide and SedgeHammer Turf Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with halosulfuron-methyl on the skin or through inhalation of spray mists, anyone mixing, loading and applying Sandea Herbicide, Permit Herbicide, or SedgeHammer Turf Herbicide must wear a long-sleeved shirt and long pants (or coveralls), chemical-resistant gloves, shoes and socks. Anyone who mixes/loads and applies SedgeHammer Turf Herbicide must wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, shoes and socks when treating roadsides and other industrial areas for horsetail with a mechanically-pressurized handgun.

The Permit Herbicide label also requires that workers do not enter treated fields to detassel seed corn for 14 days after application. For other re-entry activities, the Sandea Herbicide and Permit Herbicide labels require that workers do not enter treated fields or orchards for 12 hours after application. The SedgeHammer Turf Herbicide label requires that workers do not enter treated areas until sprays have dried. In addition, standard label statements to protect against drift during application were added to the label.

Environment

Halosulfuron-methyl can pose a risk to freshwater algae and to non-target terrestrial and aquatic vascular plants. Label statements and spray buffer zones to protect sensitive terrestrial and aquatic habitats are to be specified on the label.

To mitigate potential exposures via spray drift, spray buffer zones of 15 to 40 metres are required to protect sensitive terrestrial habitats, and spray buffer zones of 4 to 25 metres are required to protect sensitive aquatic habitats, depending on the crop. These spray buffer zones are to be specified on the product labels.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2014-05, *Halosulfuron, present as methyl ester*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

⁵

As per subsection 35(1) of the *Pest Control Products Act*.